(2) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).

(e) *Immunizations*—(1) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012 (incorporated by reference in § 170.299).

(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' available at *http://www.whitehouse.gov/omb/ fedreg_1997standards*).

(g) *Preferred language. Standard.* As specified by the Library of Congress, ISO 639–2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639–1. (incorporated by reference in § 170.299).

(h) *Smoking status. Standard.* Smoking status must be coded in one of the following SNOMED CT® codes:

(1) *Current every day smoker.* 449868002

(2) *Current some day smoker.* 428041000124106

(3) *Former smoker.* 8517006

(4) *Never smoker.* 266919005

(5) *Smoker, current status unknown.* 77176002

(6) *Unknown if ever smoked.* 266927001

(7) *Heavy tobacco smoker.* 428071000124103

(8) *Light tobacco smoker.* 428061000124105

(i) *Encounter diagnoses. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(j) *Family health history.* HL7 Version 3 Standard: Clinical Genomics; Pedigree, (incorporated by reference in § 170.299).

[75 FR 44649, July 28, 2010, as amended at 77 FR 54284, Sept. 4, 2012]

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

(a) *Encryption and decryption of electronic health information*—(1) *General.* Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2, (January 27, 2010) (incorporated by reference in § 170.299).

(2) *Exchange.* Any encrypted and integrity protected link.

(b) *Record actions related to electronic health information.* The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded.

(c) *Verification that electronic health information has not been altered in transit. Standard.* A hashing algorithm with a security strength equal to or greater than SHA–1 (Secure Hash Algorithm (SHA–1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180–4 (March 2012)) must be used to verify that electronic health information has not been altered.

(d) *Record treatment, payment, and health care operations disclosures.* The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

(e) *Record actions related to electronic health information, audit log status, and encryption of end-user devices.* (1)(i) The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at § 170.210(h) when EHR technology is in use.

(ii) The date and time must be recorded in accordance with the standard specified at § 170.210(g).

(2)(i) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed.

(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(3) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(f) *Encryption and hashing of electronic health information.* Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140–2 (incorporated by reference in § 170.299).

(g) *Synchronized clocks.* The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

(h) *Audit log content.* ASTM E2147–01(Reapproved 2009), (incorporated by reference in § 170.299)

[75 FR 44649, July 28, 2010, as amended at 77 FR 54285, Sept. 4, 2012]

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal__register/code__of__federal__regulations/*

ibr__locations.html. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the sources listed below.

(b) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org.*

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

(2) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or *http://www.astm.org/.*

(1) ASTM E2147–01 (Reapproved 2009) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved September 1, 2009, IBR approved for § 170.210.

(2) ASTM E2369–05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(3) ASTM E2369–05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for § 170.205.

(d) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333, USA (800–232–4636); *http://www.cdc.gov/ehrmeaningfuluse/.*

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) IIS: HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012, IBR approved for § 170.207.

(3) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven